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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/574,461	11/30/95	BARONE	A 16528X-0155-

EXAMINER	
PONNALURI,P	
ART UNIT	**PAPER NUMBER**
1627	34

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DATE MAILED: 03/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 08/574,461	Applicant(s) Barone et al
	Examiner P. Ponnaluri	Group Art Unit 1627

☒ Responsive to communication(s) filed on *Dec 18, 2000*.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-8, 10-15, and 37-39* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-8, 10-15, and 37-39* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

NOTE: The change of Examiner in this application.

1. The amendment filed on 12/18/00 has been fully considered and entered into the application.

2. Claims 1 and 10 have been amended with the amendment filed on 12/18/00.

3. Claims 1-8, 10-15, and 37-39 are currently pending and are being examined in this application.

4. The rejection of claims 1-8, 10-15 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lam *et al* [US Patent 5,640,489] in view of Fodor *et al* [Science 251: 767 (1991)] and applicants' disclosure of the prior art teachings, has been with drawn in view of applicants amendments (deletion of limitation 'planar surface on a') to the claims.

5. Claims 1-8, 10-15, 37-39 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of the record set forth in the previous office action (paragraph # 3).

6. Claims 1-8, 10-15, 37-39 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of the record set forth in the previous office action (paragraph # 4).

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-8, 10-15 and 37-39 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lam *et al* [US Patent 5,640,489], for the reasons set forth in the previous office action.

9. Claims 1-8, 10-15 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lam *et al* [5,640,489; 102(e) date of at least 7/2/91] in view of Holmes [US 5,679,773] and applicants' disclosure of the prior art teachings, for the reasons set forth in the previous office action.

10. Applicant's arguments, regarding the written description rejection and scope enablement rejection of record, filed on 12/18/00 have been fully considered but they are not persuasive.

Applicants have amended independent claim as "array of diverse biological polymers". Applicants point out that the specification pages 14-15 disclose that 'biological polymers are composed of biological monomers that include natural and synthetic amino acids, nucleotides, nucleosides, phosphoramidites, and carbohydrates.' Applicants refer to US Patent 5,677,195, which point out many polymers. Thus, applicants argue that the 'biological polymer' fully meet the written description and enablement rejections of record. Applicants arguments are not persuasive, because the 'biological polymer' in the specification (page 15, lines 7-13), includes agonists, antagonists of cell membrane receptors, toxins, venoms, viral epitopes, hormones, drugs, lectins, antibodies, and enzymes. However, the specification disclosure does not have sufficient guidance on how to make arrays of these compounds. The narrow scope of examples in the specification are drawn to and directed to methods for making oligonucleotide or peptide arrays, which are clearly not representative of the scope of polymer array synthesis of the presently claimed invention. The specification description is directed to specific arrays of compounds which

clearly do not provide an adequate representation regarding the open ended claimed method of monitoring polymer arrays, made by the presently claimed invention.

The specification fails to give adequate direction and guidance in the preparation of arrays of polymers commensurate in scope with biological polymers as set forth in the claims. Moreover, as one must be able to control the length of the polymers in the claims to a specified number of monomers the chemistry used for preparation of many polymers (bulk homogeneous and heterogeneous catalysis) cannot be applied. Moreover, there is no teaching commensurate with the required incorporation of labels into biological polymers, only the incorporation of labels into peptides, and nucleotides. Applicants have failed to provide working examples that are commensurate in scope with the unlimited biopolymers claimed. The breadth of the claims encompasses a literally any biological polymer such as the catalysts, antibodies, lipids, phosholipids, lectins, steroids, etc. The state of the prior art is such that methods of preparing polymers limited in the exact number of monomeric units is not widely practiced except in the nucleotide and peptide areas. Thus, one has to develop synthetic routes capable of limiting the exact number of monomeric units incorporated into any polymer (generally by step wise addition of monomers) and means of labeling the corresponding resulting polymers. The art is inherently unpredictable because predicting a priori how to prepare any single polymer cannot be done with certainty. The situation is compounded by the necessity that the chemistry must be flexible enough to accommodate differing subunits and still result in the production of the expected member in each position of the array. Thus, it would require undue experimentation to make and use the

invention commensurate in scope with that claimed in the absence of explicit guidance as to a means of preparing and labeling any polymer as set forth above. The rejections of record have been maintained for the reasons of the record.

11. Applicant's arguments filed on 12/18/00, regarding the rejections over Lam et al, have been fully considered but they are not persuasive.

Applicants argue that Lam et al fail to teach or suggest the claimed step of synthesizing a 'preselected array' of diverse biological polymers connected to cleavable linkers on solid support. Applicants arguments have been considered but are not persuasive, because the reference teaches methods for synthesis of peptides with specific structure (see column 39, section 10.1.1, and example 11, in columns 43-; and example 12, in column 46), not only the random libraries. The reference teaches that the method may be used for synthesis of random peptides as well as for the synthesis of a peptide library that comprises predetermined sequences (see column 10, lines 57-59); and the synthesis of predetermined sequences involves the use of specific Nα-Boc-, Nα-Fmoc- or other appropriately protected amino acids during specific coupling steps (see column 10, lines 59-61) .

Applicants argue that 'Lam teaches synthesis of a random library of biopolymers on beads, wherein each bead contains a single biopolymer and not a spatially defined pattern of polymers on a solid support. Applicants arguments are not persuasive, since the solid substrate of the instant claims may refer to beads, which are arranged in a spatially defined pattern, such as in a microtiter plate. The reference also teaches that the beads are partitioned in a microtiter plate wells. The

reference teaches that the solid phase support is not limited to a specific type of support, and solid phase supports include gels, resins, plastic films, glass beads, cotton, plastic beads, alumin gels. The suitable solid support may be selected on the basis of desired end use and suitability for various protocols (see column 15, lines 39-46). And also even though Lam et al teach that each bead contains a single biopolymer (e.g., a single peptide attached to a bead), a library consists of a lot of such beads together. Thus, the biopolymers attached to more than one bead refer to spatially defined pattern. The beads together are referred to as solid support. Applicants refer to prior art section of the reference patent to conclude that Lam et al teaches against a preselected array of biological polymers on solid support as claimed. Applicants arguments are not persuasive.

Applicants argue that the method of Lam et al is not concerned with examining the length of synthesized species after the complete, overall synthesis of the random biopolymers because Lam et al teaches examining and assuring the length of biopolymers measuring each synthetic coupling step of an overall synthesis. Applicants argue that the Lam et al provides no motivation, and teaches away from any need or desire to measure the length of polymers or the presence of truncated polymers by measuring the size of the polymers cleaved from biosynthetic support after overall synthesis is complete. Applicants argue that the complete coupling method taught by Lam et al is not applicable to synthesizing a preselected array of diverse biopolymers on a solid support. Applicants arguments have been considered but are not persuasive, because Lam et al teach separately cleaving the collections of polymers from the support beads to form separate mixtures and measuring the components present via a property which reads on measuring a

"property" of the mixture of unbound polymers as an indicator of the efficiency of the synthesizing step (see figure 3 and col. 34, line 60 - col. 35, line 55). The rejections have been maintained for the reasons of the record.

12. Applicant's arguments filed on 12/18/00, regarding the rejection of claims over Lam et al (US Patent 5,640,489) in view of Holmes et al (US Patent 5,679,773) have been fully considered but they are not persuasive.

Applicants argue that Lam et al teach against the use of a preselected array of biological polymers on a solid support. Applicants arguments are not persuasive, because Lam et al teach that the method may be used for synthesis of random peptides as well as for the synthesis of a peptide library that comprises predetermined sequences (see column 10, lines 57-59). Thus, Lam et al teach predetermined polymer on a solid support. Applicants argue that Lam et al do not provide motivation to combine the references. Applicants arguments are not persuasive, because Lam et al teach synthesis of predetermined polymers on the solid support. Thus the rejections of record have been maintained.

13. No claims are allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

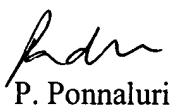
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached at (703)308-2439. The fax number for this group is (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.



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